May 20, 2021

Vascular Solutions, Inc.
Matt Nienstedt
Regulatory Affairs Associate
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K103405
Trade/Device Name: Pronto V4 extraction catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Matt Nienstedt:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 22, 2010. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.05.20 09:47:10 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vascular Solutions, Inc.
c/o Mr. Matt Nienstedt
6464 Sycamore Court
Minneapolis, MN 55369

DEC 22 2010

Re: K103405
Trade/Device Name: Pronto® V4 Extraction Catheter
Common Name: Catheter, Embolectomy
Regulation Number: 21 CFR 870.5150
Regulatory Class: II
Product Code: DXE
Dated: December 14, 2010
Received: December 15, 2010

Dear Mr. Nienstedt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

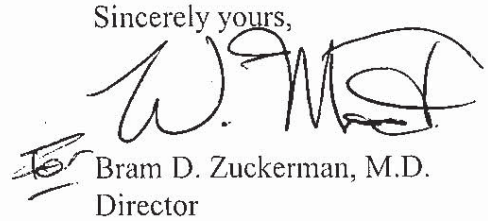
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 2 2 2010

# Indications for Use

**510(k) Number (if known):** K103405

**Device Name**: Pronto V4 extraction catheter

**Indications for Use**:

The Pronto catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

| | | |
|---|---|---|
| Prescription Use _X_<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number _____

DEC 2 2 2010

## 2 510(k) Summary

[As required by 21 CFR 807.92]

**510(k) Number:** K103405 **Date Prepared: December 20, 2010**

### Submitter's Information / Contact Person


**Manufacturer**

Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

**Contact Person**

Matt Nienstedt
Regulatory Affairs Associate
Tel: 763.656.4317 (direct)
Fax: 763.656.4253
Email: mnienstedt@vascularsolutions.com

**Alternate Contact Person**

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Senior Regulatory Affairs Operations Associate
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Fax: 763.656.4253
Email: souellette@vascularsolutions.com


### General Information

| | |
|---|---|
| **Trade Name** | Pronto® V4 extraction catheter |
| **Common / Usual Name** | Extraction catheter |
| **Classification Name** | 21 CFR 870.5150, Embolectomy Catheter |
| **Predicate Device** | Pronto V3 extraction catheter (K083784 - Vascular Solutions, Inc.) |

### Device Description

The Pronto V4 extraction catheter (Pronto) is a dual lumen rapid exchange catheter that has a working length of approximately 138 cm and is packaged with related accessories. The smaller wire lumen of the catheter is able to accommodate guidewires ≤0.014 inches in diameter. The larger extraction lumen allows for the removal of thrombus by use of the included 30 mL syringes through the extension line and stopcock. The catheter has a stiff proximal region and a flexible distal region. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitate advancement of the catheter into the blood vessel and maximize extraction of thrombus

through the extraction lumen. The catheter contains a radiopaque marker band located approximately 2 mm from the distal tip. The distal 18 cm of the catheter has a hydrophilic coating to enhance deliverability to the target vasculature. The device has positioning marks located at 95 cm and 105 cm from the distal tip, respectively. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of catheter to the included extension line, stopcock, and 30 mL syringes. A filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis of any thrombus.

**Intended Use / Indications**

The Pronto catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

**Technological Characteristics**

The Pronto V4 and predicate Pronto V3 devices have the following characteristics in common:

- Compatibility with 0.014 inch guidewires
- Shaft construction - several thermoplastics reflowed together.
- Silva tip with radiopaque marker band
- Positioning marks
- Hydrophilic coating
- Hub configuration - Both the predicate and subject device have hubs that are compatible with ISO 594-1 and ISO 594-2 compliant luer fittings
- Sterilized by ethylene oxide
- Provided with identical accessories
- Packaged in identical sterile pouch and retail box

The Pronto V4 and predicate Pronto V3 devices differ in the following:

- Hub and shaft materials and construction
- The Pronto V4 extraction catheter is offered in additional sizes (5.5F, 7F, and 8F)

**Substantial Equivalence and Summary of Studies**

The Pronto V4 extraction catheters are substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design was qualified through the following tests:

- Simulated anatomy/concomitant device use
- Hydrophilic coating integrity and particulates
- Thrombus aspiration
- Kink resistance
- Air aspiration
- Tensile
- Torque
- Dimensional verifications
- Radiopacity
- Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation/intracutaneous reactivity
    - Acute systemic toxicity
    - Material mediated pyrogens
    - Hemocompatibility
        - Hemolysis
        - Coagulation
        - Prothrombin time
        - Hemotological parameters
        - Complement activation
        - Thrombogenicity

Results of the verification testing and biomaterial assessments met the specified acceptance criteria and did not raise new safety or performance questions.